

GP 1645
DT
1-18-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nazarenko *et al.*

Appl. No. 09/599,594

Filed: June 22, 2000

For: **Improved Primers and Methods for
the Detection and Discrimination
of Nucleic Acids**



Art Unit: 1645

Examiner: To Be Assigned

Atty. Docket: 0942.4980002/RWE/KKV

RECEIVED

Information Disclosure Statement

JAN 17 2001

Commissioner for Patents
Washington, DC 20231

TECH CENTER 1600/2900

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Document AS4 is in a foreign language. An English translation is not readily available. Document AS4 appears to show that in FRET (fluorescence resonance energy transfer) (wherein energy is passed non-radiatively over a long distance (10-100 Å) between a donor molecule, which is a fluorophore, and an acceptor molecule), the donor absorbs a photon and transfers this energy non-radiatively to the acceptor. Further, document AS4 appears to show that the efficiency of energy transfer is proportional to $D \times 10^{-6}$, where D is

the distance between the donor and acceptor. Effectively, this means that FRET can most efficiently occur up to distances of about 70 Å.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

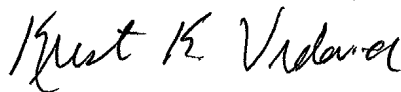
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

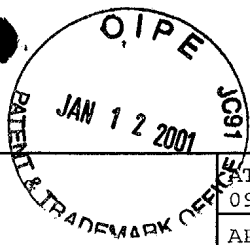
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Kristin K. Vidovich
Attorney for Applicants
Registration No. 41,448

Date: Jan. 12, 2001
1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

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FORM PTO-1449

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	4,358,535	11/09/1982	Falkow et al.	435	5	12/08/1980
	AB1	4,446,237	05/01/1984	Berninger	436	504	03/27/1981
	AC1	4,563,417	01/07/1986	Albarella et al.	435	6	01/07/1986
	AD1	4,581,333	04/08/1986	Kourilsky et al.	435	6	04/29/1982
	AE1	4,582,788	04/15/1986	Erlich	435	6	01/07/1983
	AF1	4,582,789	04/15/1986	Sheldon, III et al.	435	6	12/18/1984
	AG1	4,683,194	07/28/1987	Saiki et al.	435	6	03/28/1985
	AH1	4,683,202	07/28/1987	Mullis	435	91	10/25/1985
	AI1	4,889,818	12/26/1989	Gelfand et al.	435	194	06/17/1987
	AJ1	4,965,188	10/23/1990	Mullis et al.	435	6	06/17/1987
	AK1	5,047,342	09/10/1991	Chatterjee	435	194	08/10/1989

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	EP 0 50,424	09/24/1981	Europe			Yes No
	AM1	EP 0 84,796	01/11/1983	Europe			Yes No
	AN1	EP 0 144 914	11/29/1984	Europe			Yes No
	AO1	EP 0 119 448	02/10/1984	Europe			Yes No
	AP1	EP 0 201 184	03/27/1986	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)


	AR	<u>1</u>	Abe, T., et al., "Specific inhibition of influenza virus RNA polymerase and nucleoprotein gene expression by circular dumbbell RNA/DNA chimeric oligonucleotides containing antisense phosphodiester oligonucleotides," <i>FEBS Lett.</i> 425:91-96, Elsevier Science Publishers B.V., Amsterdam, Netherlands (1998).
	AS	<u>1</u>	Austermann, S., et al., "Inhibition of Human Immunodeficiency Virus Type 1 Reverse Transcriptase by 3'-Blocked Oligonucleotide Primers," <i>Biochem. Pharmacol.</i> 43:2581-2589, Elsevier Science, Oxford, England (1992).
	AT	<u>1</u>	Barnes, W.M., "The fidelity of Taq polymerase catalyzing PCR is improved by an N-terminal deletion," <i>Gene</i> 112:29-35, Elsevier Science Publishers B.V., Amsterdam, Netherlands (1992).

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	AA2	5,079,352	01/07/1992	Gelfand et al.	536	27	05/15/1990
	AB2	5,143,854	09/01/1992	Pirrung et al.	436	518	03/07/1990
	AC2	5,137,814	08/11/1992	Rashtchian et al.	435	91	06/14/1991
	AD2	5,194,370	03/16/1993	Berninger et al.	436	501	05/16/1990
	AE2	5,244,797	09/14/1993	Kotewicz et al.	435	194	03/18/1991
	AF2	5,252,743	10/12/1993	Barrett et al.	548	303.7	11/13/1990
	AG2	5,270,179	12/14/1993	Chatterjee	435	69.1	01/28/1992
	AH2	5,334,515	08/02/1994	Rashtchian et al.	435	91.2	03/29/1993
	AI2	5,338,671	08/16/1994	Scalice et al.	435	91.2	10/07/1992
	AJ2	5,348,853	09/20/1994	Wang et al.	435	6	12/16/1991
	AK2	5,374,553	12/20/1994	Gelfand et al.	435	252.3	08/13/1990

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL2	EP 0 237 362	03/13/1987	Europe			Yes No
	AM2	EP 0 258 017	08/21/1987	Europe			Yes No
	AN2	EP 0 329 822	08/26/1988	Europe			Yes No
	AO2	WO 88/10315	12/29/1988	WIPO			Yes No
	AP2	WO 89/06700	07/27/1989	WIPO			Yes No

	AR	<u>2</u>	Bonnet, G., et al., "Thermodynamic basis of the enhanced specificity of structured DNA probes," <i>Proc. Natl. Acad. Sci. USA</i> 96:6171-6176, National Academy of Sciences of the USA, Washington, D.C. (May 1999).
	AS	<u>2</u>	Cardullo et al, "Detection of nucleic acid hybridization by non radiative fluorescence resonance energy transfer," <i>Proc. Natl. Acad. Sci. USA</i> 85:8790-8794, National Academy of Sciences of the USA, Washington, D.C. (1988).
	AT	<u>2</u>	Chedin, F., et al., "Novel homology of replication protein A in archaea: implications for the evolution of ssDNA-binding proteins," <i>TIBS</i> 23:273-277, International Union of Biochemistry and Elsevier Trends Journal, Cambridge, England (1998).

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	AA3	5,436,149	07/25/1995	Barnes	435	194	02/19/1993
	AB3	5,436,327	07/25/1995	Southern et al.	536	25.34	10/21/1989
	AC3	5,445,934	08/29/1995	Fodor et al.	435	6	10/30/1992
	AD3	5,449,603	09/12/1995	Nielson et al.	435	6	10/24/1989
	AE3	5,455,166	10/03/1995	Walker	435	91.2	01/09/1992
	AF3	5,512,462	04/30/1996	Cheng	435	91.2	02/25/1994
	AG3	5,578,467	11/26/1996	Schuster et al.	435	91.2	05/20/1994
	AH3	5,587,287	12/24/1996	Scalice et al.	435	6	04/07/1994
	AI3	5,593,840	01/14/1997	Bhatnagar et al.	435	6	06/05/1995
	AJ3	5,594,183	01/14/1997	Colin	73	864.52	07/26/1994
	AK3	5,595,890	01/21/1997	Newton et al.	435	91.2	02/17/1995

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL3	WO 90/03446	04/5/1990	WIPO			Yes No
	AM3	WO 92/06188	04/16/1992	WIPO			Yes No
	AN3	WO 92/06200	04/16/1992	WIPO			Yes No
	AO3	WO 92/14845	09/03/1992	WIPO			Yes No
	AP3	EP 0 684 315	03/13/1995	Europe			Yes No

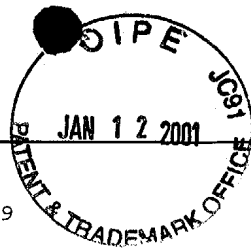
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Clegg, R.M., et al., "Fluorescence Resonance Energy Transfer Analysis of the Structure of the Four-Way DNA Junction," <i>Biochem.</i> 31:4846-4856, American Chemical Society, Washington D.C. (1992).
	AS	3	Clegg, R.M., "Fluorescence Resonance Energy Transfer and Nucleic Acids," <i>Methods Enzymol.</i> 211:353-388, Academic Press Inc., New York, NY (1992).
	AT	3	Clegg, R.M., et al., "Observing the helical geometry of double-stranded DNA in solution by fluorescence resonance energy transfer," <i>Proc. Natl. Acad. Sci. USA</i> 90:2994-2998, National Academy of Sciences of the USA, Washington, D.C. (1993).

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	AA4	5,599,695	02/04/1997	Pease et al.	435	91.1	02/27/1995
	AB4	5,605,824	02/25/1997	Nielson et al.	435	194	06/16/1993
	AC4	5,614,365	03/25/1997	Tabor et al.	435	6	11/10/1994
	AD4	5,639,611	06/17/1997	Wallace et al.	435	6	11/09/1994
	AE4	5,646,019	07/08/1997	Nielson et al.	435	91.5	04/07/1994
	AF4	5,668,005	09/16/1997	Kotewicz et al.	435	194	03/12/1996
	AG4	5,728,526	03/17/1998	George, Jr. et al.	435	6	01/07/1995
	AH4	5,763,170	06/09/1998	Raybuck	435	6	06/05/1995
	AI4	5,773,257	06/30/1998	Nielson et al.	435	91.1	06/06/1995
	AJ4	5,800,992	09/01/1998	Fodor et al.	435	6	06/25/1996
	AK4	5,837,832	11/17/1998	Chee et al.	536	22.1	05/16/1995

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL4	WO 96/10640	04/11/1996	WIPO			Yes No
	AM4	EP 0 436 644 B1	04/17/1996	Europe			Yes No
	AN4	EP 0 795 612 A2	09/17/1997	Europe			Yes No
	AO4	WO 98/35060	08/13/1998	WIPO			Yes No
	AP4	WO 98/47921	10/29/1998	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Flaman, J.-M., et al., "A rapid PCR fidelity assay," <i>Nucl. Acids Res.</i> 22:3259-3260, Oxford University Press, Oxford, England (1994).
	AS	4	Forster, Z., "Experimentelle und theoretische Untersuchung des zwischenmolekularen Übergangs von Elektronenanregungsenergie," <i>Z. Naturforsch</i> 4A:321-327, Verlag der Zeitschrift für Naturforschung, Tübingen, Germany (1949).
	AT	4	Gerard, G.F., et al., "cDNA Synthesis by Moloney Murine Leukemia Virus Rnase H-Minus Reverse Transcriptase Possessing Full DNA Polymerase Activity," <i>FOCUS</i> 14:91-93, Life Technologies, Inc., Gaithersburg, MD (1992).

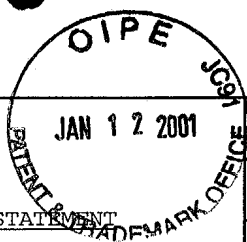
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA5	5,846,729	12/08/1998	Wu et al.	435	6	07/01/1997
	AB5	5,866,336	02/02/1999	Nazarenko et al.	435	6	01/03/1997
	AC5	5,869,251	02/09/1999	Schuster et al.	435	6	11/25/1996
	AD5	5,876,930	03/02/1999	Livak et al.	435	6	11/15/1995
	AE5	5,925,517	07/20/1999	Tyagi, et al.	435	6	05/12/1995
	AF5	5,948,899	09/07/1999	Arnold, Jr. et al.	536	24.3	06/05/1995
	AG5	5,952,172	09/14/1999	Mende et al.	435	6	06/12/1997
	AH5	6,037,130	03/14/2000	Tyagi, et al.	435	6	07/28/1998
	AI5	6,048,690	04/11/2000	Heller et al.	435	6	05/14/1997
	AJ5	6,090,552	07/18/2000	Nazarenko et al.	435	6	07/11/1997
	AK5	5,714,331	02/03/1998	Buchardt et al.	435	6	07/24/1996

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL5	WO 99/10366	03/04/1999	WIPO			Yes No
	AM5	EP 0 795 612 A3	03/24/1999	Europe			Yes No
	AN5						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Holland, P.M., et al., "Detection of specific polymerase chain reaction product by utilizing the 5'→3' exonuclease activity of <i>Thermus aquaticus</i> DNA polymerase," <i>Proc. Natl. Acad. Sci. USA</i> 88:7276-7280, National Academy of Sciences of the USA, Washington, D.C. (1991).
	AS	5	Houts, G.E., et al., "Reverse Transcriptase from Avian Myeloblastosis Virus," <i>J. Virol.</i> 29:517-522, American Society for Microbiology, Baltimore, MD (1979).
	AT	5	Idriss, H., and Stammers, D.K., "Inhibition of HIV-1 Reverse Transcriptase by Defined Template/Primer DNA Oligonucleotides: Effect of Template Length and Binding Characteristics," <i>J. Enzyme Inhib.</i> 8:91-112, Harwood Academic, Chur, New York (1994).

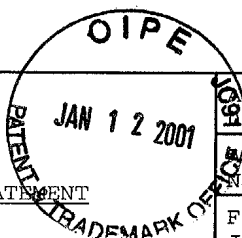
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	AA6	5,736,336	04/07/1998	Buchardt et al.	435	6	05/01/1997
	AB						
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Jendis, J., et al., "Inhibition of Replication of Fresh HIV Type 1 Patient Isolates by a Polypurine Tract-Specific Self-Complementary Oligodeoxynucleotide," <i>AIDS Res. Human Retrov.</i> 12:1161-1168, Mary Ann Leibert, Inc., Publishers, Larchmont, NY (1996).
	AS	6	Ju, J., et al., "Fluorescence energy transfer dye-labeled primers for DNA sequencing and analysis," <i>Proc. Natl. Acad. Sci. USA</i> 92:4347-4351, National Academy of Sciences of the USA, Washington, D.C. (1995).
	AT	6	Kainz, A.P., et al., "Specificity-Enhanced Hot-Start PCR: Addition of Double-Stranded DNA Fragments Adapted to the Annealing Temperature," <i>BioTechniques</i> 28:278-282, Eaton Publishing Company, Natick, MA (February 2000).

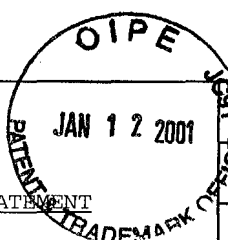
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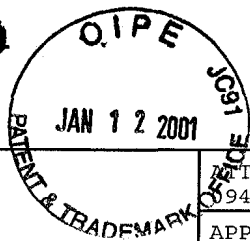
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Kelly, T.J., et al., "Identification and characterization of a single-stranded DNA-binding protein from the archaeon <i>Methanococcus jannaschii</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 95:14634-14639, National Academy of Sciences of the USA, Washington, D.C. (1998).
	AS	7	Kleppe, K., et al., "Studies on Polynucleotides. XCVI. Repair Replications of Short Synthetic DNA's as Catalyzed by DNA Polymerases," <i>J. Mol. Biol.</i> 56:341-361, Academic Press, Inc., New York, NY (1971).
	AT	7	Kotewicz, M.L., et al., "Isolation of cloned Moloney murine leukemia virus reverse transcriptase lacking ribonuclease H activity," <i>Nucl. Acids Res.</i> 16:265-277, Oxford University Press, Oxford, England (1988).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
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	AR	8	Kuwasaki, T., et al., "Hairpin Antisense Oligonucleotides Containing 2'-Methoxynucleosides with Base-Pairing in the Stem Region at the 3'-end: Penetration, Localization, and Anti-HIV Activity," <i>Biochem. Biophys. Res. Commun.</i> 228:623-631, Academic Press, Inc., Orlando, FL (1996).
	AS	8	Kwoh, D.Y., et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," <i>Proc. Natl. Acad. Sci. USA</i> 86:1173-1177, National Academy of Sciences of the USA, Washington, D.C. (1989).
	AT	8	Lawyer, F.C., et al., "High-Level Expression, Purification, and Enzymatic Characterization of Full-Length <i>Thermus aquaticus</i> DNA Polymerase and a Truncated Form Deficient in 5' to 3' Exonuclease Activity," <i>PCR Meth. Appl.</i> 2:275-287, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY (1993).

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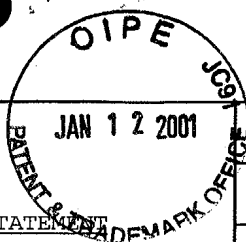
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Lee, L.G., et al., "Allelic discrimination by nick-translation PCR with fluorogenic probes," Nucl. Acids Res. 21:3761-3766, Oxford University Press, Oxford, England (1993).
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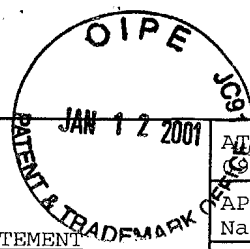
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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
942.4980002/RWE/KKVAPPLICATION NO.
09/599,594APPLICANT
Nazarenko et al.FILING DATE
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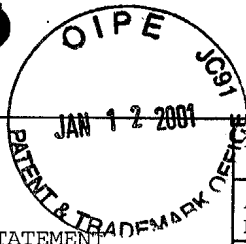
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	AR	<u>10</u>	Maury, G., et al., "Template. Phosphorothioate Oligonucleotides Duplexes As Inhibitors of HIV-1 Reverse Transcriptase," <i>Biochem. Biophys. Res. Commun.</i> 186:1249-1256, Academic Press, Inc., Orlando, FL (1992).
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	AT	<u>10</u>	Nakaya, T., et al., "Decoy Approach Using RNA-DNA Chimera Oligonucleotides To Inhibit the Regulatory Function of Human Immunodeficiency Virus Type 1 Rev Protein," <i>Antimicrobiol. Agents Chemother.</i> 41:319-325, American Society For Microbiology Washington D.C. (1997).

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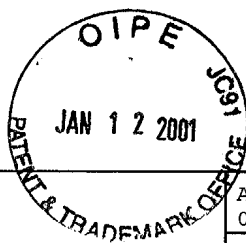
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	AR	<u>11</u>	Nazarenko, I.A., et al., "A closed tube format for amplification and detection of DNA based on energy transfer," Nucl. Acids Res. 25:2516-2521, Oxford University Press, Oxford, England (1997).
	AS	<u>11</u>	Ozaki, H., and McLaughlin, L.W., "The estimation of distances between specific backbone-labeled sites in DNA using fluorescence resonance energy transfer," Nucl. Acids Res. 20:5205-5214, Oxford University Press, Oxford, England (1992).
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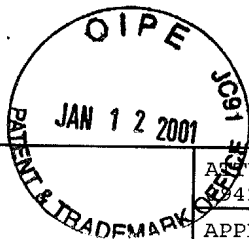
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	AR	<u>12</u>	Paris, P.L., et al., "Probing DNA sequences in solution with a monomer-excimer fluorescence color change," <i>Nucl. Acids Res.</i> 26:3789-3793, Oxford University Press, Oxford, England (1998).
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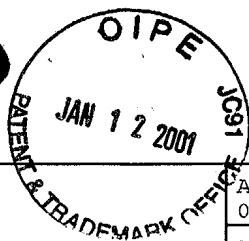
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	AR	<u>13</u>	Schneider, D.J., et al., "High Affinity ssDNA Inhibitors of the Reverse Transcriptase of Type 1 Human Immunodeficiency Virus," <i>Biochem.</i> 34:9599-9610, American Chemical Society, Washington D.C. (1995).
	AS	<u>13</u>	Selvin, P.R., "Fluorescence Resonance Energy Transfer," <i>Methods Enzymol.</i> 246:300-334, Academic Press Inc., New York, NY (1995).
	AT	<u>13</u>	Selvin, P.R., and Hearst, J.E., "Luminescence energy transfer using a terbium chelate: Improvements on fluorescence energy transfer," <i>Proc. Natl. Acad. Sci. USA</i> 91:10024-10028, National Academy of Sciences of the USA, Washington, D.C. (1994).

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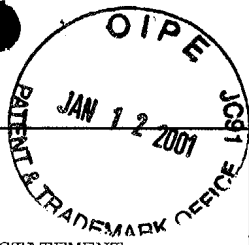
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	AR	<u>14</u>	Soltis, D.A., and Skalka, A.M., "The α and β chains of avian retrovirus reverse transcriptase independently expressed in <i>Escherichia coli</i> : Characterization of enzymatic activities," <i>Proc. Natl. Acad. Sci. USA</i> 85:3372-3376, National Academy of Sciences of the USA, Washington, D.C. (1988).
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	AR	15	Wang, Y., et al., "Rapid Sizing of Short Tandem Repeat Alleles Using Capillary Array Electrophoresis and Energy-Transfer Fluorescent Primers," <i>Anal. Chem.</i> 67:1197-1203, American Chemical Society, Washington D.C. (1995).
	AS	15	Wu, D.Y., et al., "Allele-specific enzymatic amplification of β -globin genomic DNA for diagnosis of sickle cell anemia," <i>Proc. Natl. Acad. Sci. USA</i> 86:2757-2760, National Academy of Sciences of the USA, Washington, D.C. (1989).
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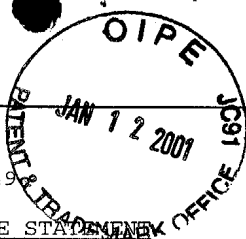
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	AR	<u>16</u>	Xu, D., et al., "Melting and Premelting Transitions of an Oligomer Measured by DNA Base Fluorescence and Absorption," <i>Biochem.</i> 33:9592-9599, American Chemical Society, Washington D.C. (1994).
	AS	<u>16</u>	Yamana, K, et al., "Flourescent-labeled Oligonucleotides that Exhibit a Measurable Signal in the Presence of Complementary DNA," <i>Nucl. Acids Symp. Ser.</i> 27:135-136, London Information Retrieval, London, England (1992).
	AT	<u>16</u>	"Amplifluor™ Universal Amplication & Detection System," Intergen Company Catalog, 4 pages, Purchase, NY (1999).

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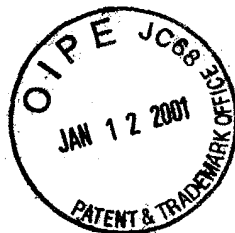
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DP

Applicant: Nazarenko *et al.*
Application No.: 09/599,594
Filed: June 22, 2000
For: Improved Primers and Methods for the Detection and Discrimination of Nucleic Acids

Due Date: None
Art Unit: 1645
Examiner: To be assigned
Docket: 0942.4980002
Atty: RWE/KKV

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